



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 23, 2015

ONTEX BVBA
% Rachel Paul
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Re: K142786
Trade/Device Name: Ontex Unscented Tampons with Colored Plastic Applicators
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: April 30, 2015
Received: May 18, 2015

Dear Rachel Paul,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142786

Device Name

Ontex Unscented Tampons with Colored Plastic Applicators

Indications for Use (Describe)

The Ontex Unscented Tampons with Colored Plastic Applicators are inserted into the vagina to absorb menstrual discharge.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary For Ontex Unscented Tampons with Colored Plastic Applicators

510(k) Number: K142786

1. Submission Sponsor

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3. Date Prepared

30/04/2015

4. Device Identification

Trade/Proprietary Name:	Ontex Unscented Tampons with Colored Plastic Applicators
Common/Usual Name:	Unscented Menstrual Tampon
Classification Name:	Unscented Menstrual Tampon
Classification Regulation:	21 CFR 884.5470
Product Code:	HEB
Device Class:	Class II
Classification Panel:	OBGYN, Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons	K122603
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6. Device Description

Tampons included in this submission are conventional unscented menstrual tampons consisting of an absorbent pledget (viscose material in a W-shape wadding form), polyester/cotton withdrawal cord, and a polymeric overwrap. The tampon component of this submission is identical to that cleared in the predicate submission (K122603).

Tampons included in this submission are placed in the vagina using a polyethylene applicator. The applicator is available in two sizes: full size (long) or compact size. The full size applicator is ready for use. The compact size consists of an inner and outer tube that requires the inner tube to be retracted prior to use. Applicators included in this submission are provided in different colors including green, yellow, lilac, orange and pink.

7. Indication for Use Statement

The Ontex Unscented Tampons with Colored Plastic Applicators are inserted into the vagina to absorb menstrual discharge.

8. Substantial Equivalence Discussion

The following table compares the Unscented Tampons with Colored Plastic Applicators to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A –General Comparison of Characteristics

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	Ontex Unscented Tampons with Colored Plastic Applicators (K142786)	Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons (K122603)	Colored applicators tubes
510(k) Number	K142786	K122603	NA.
Product Code	HEB	HEB	Same.
Regulation Number	21 CFR PART 884.5470	21 CFR PART 884.5470	Same.
Regulation Name	Unscented menstrual tampons.	Unscented menstrual tampons.	Same.
Indications for Use	The Ontex Unscented Tampons with Colored Plastic Applicators are	The Ontex Unscented Digital and Plastic and Cardboard Applicator	Only menstrual discharge for K142786.

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	Ontex Unscented Tampons with Colored Plastic Applicators (K142786)	Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons (K122603)	Colored applicators tubes
	inserted into the vagina to absorb menstrual discharge.	Tampons, available in light, regular, super and super plus absorbency are inserted into the vagina and used to absorb menstrual or other vaginal discharge.	
Overall Design	W wadding tampon with plastic applicators of full size (long) and compact size	Roll wadding tampon digital (without applicator) W wadding tampon type with a plastic/cardboard applicator in full size (long) and in compact size	No digital tampon, or cardboard applicator.
Unscented/Scented	Unscented	Unscented	Same
Dimensions Specifications (mm)	Total length (in ready to push position): 110 - 135 Outside diameter (outer tube): 13.5 - 18.2	Total length (in ready to push position): 110 - 135 Outside diameter (outer tube): 13.5 - 18.2	Same
Weight Specifications (g)	3.6 – 8.1	3.6 – 8.1	Same
Absorbent Pledget	Viscose	Viscose	Same
Withdrawal Cord	Cotton polyester	Cotton polyester	Same
Applicator	Plastic –polyethylene including pigments	Compact size: Plastic – polyethylene Full size (long): plastic – polyethylene with white pigment	Different with pigments of color green, lilac, orange, yellow or pink
	NA	Cardboard - Paper	Different, no cardboard applicator
Absorbencies	<6g, 6-9g, 9-12g, 12-15g	<6g, 6-9g, 9-12g, 12-15g	Same
Expulsion Force	< 6N	< 6N	Same
Fibre Shedding	< 1mg	< 1mg	Same
Cord Strength	> 60N	> 60N	Same
Packaging	Primary packaging:	Primary packaging:	Same

Manufacturer	ONTEX	ONTEX	SIGNIFICANT DIFFERENCES
Trade Name	Ontex Unscented Tampons with Colored Plastic Applicators (K142786)	Ontex Unscented Digital and Plastic and Cardboard Applicator Tampons (K122603)	Colored applicators tubes
	individual polymeric wrapper Secondary packaging: cardboard box	individual polymeric wrapper Secondary packaging: cardboard box	
Sterile	no	no	Same
Single-Use	yes	yes	Same

9. Non-Clinical Performance Data

The predicate and the subject device are exactly the same at the exception of the presence of different colored pigments in the plastic applicator tubes.

The following tests were performed to support substantial equivalence:

- Extraction 24h at 37°C in water
- Visual inspection and spectrophotometric analysis
- Gravimetric analysis
- Gas chromatography and mass spectrophotometry (GC-MS)

After extraction of each colored applicator and additional testing for determination of possible leachates, the test results showed there is no potential for leachables to migrate from the colored plastic tampon applicators in water.

A toxicological risk assessment explains that the color variants of the tampon applicator would not be expected to cause any adverse effects under normal and reasonably foreseeable conditions of use and also supports the safety of each of the color variants.

10. Performance Testing – Bench

The predicate and the subject device are exactly the same at the exception of the presence of different colored pigments in the plastic applicator tubes.

The following test was performed to support substantial equivalence:

- Expulsion force applicator
- Expulsion force met the specifications as defined for the predicate.

The modification has no impact on the absorptive capacity (Syngena), fiber loss and cord strength of the device. The predicate testing specifications are still applicable to the subject device for these tests.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The proposed device and the predicate have the same intended use. The technological characteristics are identical or similar.

Ontex has completed a number of tests in order to demonstrate that the Ontex Unscented Tampons with Colored Plastic Applicators meet the applicable requirements for bench testing and that there is no potential for leachables to migrate. The toxicological risk assessment supports the safety of each of the color variants under normal and reasonably foreseeable conditions of use.

It has been shown in this 510(k) submission that the difference between the Ontex Unscented Tampons with Colored Plastic Applicators and the predicate devices do not raise any different questions regarding its safety and effectiveness. The Ontex Unscented Tampons with Colored Plastic Applicators, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.